Ohio Medical Corporation®

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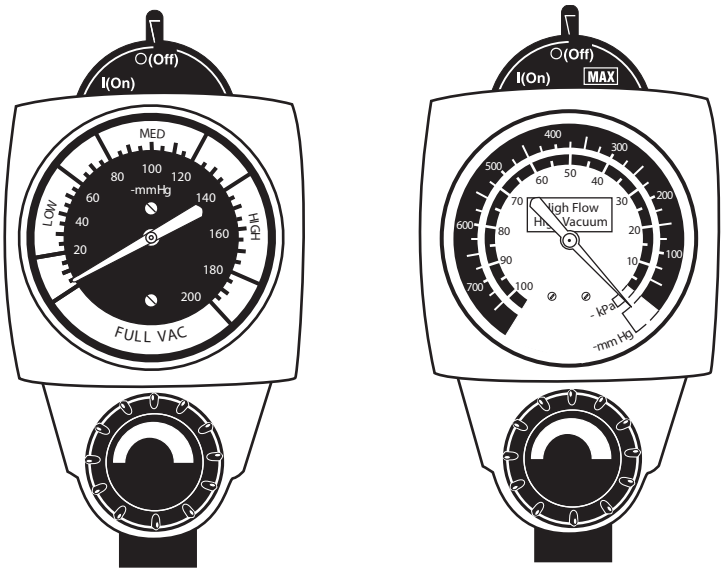
Continuous Vacuum Regulators

Service Manual



RX ONLY

6700-0072-000 (Rev.5 (11/2012)

User Responsibility

This Product will perform as described in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A malfunctioning Product should not be used. Parts that are broken, missing, plainly worn, destroyed or contaminated, should be replaced immediately. Should such repair or replacement become necessary, Ohio Medical recommends that a telephonic or written request for service advice be made to the nearest Ohio Medical Service Office. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by Ohio Medical, or altered without the prior written approval of Ohio Medical's Safety Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alterations by anyone other than Ohio Medical Corporation.

Technical Competence

The procedures described in this service manual should be performed by competent individuals who have a general knowledge of and experience with devices of this nature. No repairs should ever be undertaken or attempted by anyone not having such qualifications.

Genuine replacement parts manufactured or sold by Ohio Medical must be used for all repairs.

Read completely through each step in every procedure before starting the procedure; any exceptions may result in a failure to properly and safely complete the attempted procedure.

Abbreviations

CCW	Counter-clockwise (Anti-clockwise)
MAX	Full Line Vacuum
inHg	Inches of Mercury
kPa	Kilopascals (kPa x 7.50 = mmHg)
LPM	Liters per minute
mmHg	Millimeters of mercury (mmHg x .133 = kPa)
mL	Milliliters
°C	Degrees Celsius
°F	Degrees Fahrenheit
N-m	Newton-Meter (N-m x .737 = ft-lb)
ft-lb	Foot-Pound Force (ft-lb x 1.356 = N-m)
oz	Ounces
NPT	National Pipe Thread (USA)
NPTF	National Pipe Thread Female (USA)
MPTS	Multi-Purpose Therapy Stand
gal	Gallon
PTFE	Polytetrafluoroethylene

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1/Precautions

1.1 Definitions

Note: A Note provides additional information to clarify a point in the text.

Important: An Important statement is similar to a note but of greater emphasis.

CAUTION : A CAUTION statement is used when the possibility of damage to the equipment exists.

WARNING: **A WARNING statement is used when the possibility of injury to the patient or the operator exists.**

⚠ = Alerts you to a warning or caution in the text.

MAX = maximum

High Flow
High Vacuum = high flow, high vacuum

High Flow
Low Vacuum = high flow, low vacuum

| (On) = On

O (Off) = Off

1.2 Warnings

The pre-use checkout procedure (Section 4.5 Pre-Use Checkout Procedure) must be performed before using this equipment on each patient. If the regulator fails any part of the pre-use checkout procedure, it must be removed from service and repaired by qualified service personnel.

Connect the vacuum regulator to the vacuum source only. Connection to pressure sources even momentarily could injure the patient or operator and damage the equipment.

Always connect the regulator to the vacuum source and check its operation before attaching the patient connection.

The fitting port of the regulator must be occluded when setting the prescribed suction level. This prevents the patient from receiving higher than required suction levels.

Do not use this device in the presence of flammable anesthetics. Static charges may not dissipate and a possible explosion hazard exists in the presence of these agents.

After patient use, regulators may be contaminated. Handle in accordance with your hospital's infection control policy.

Clean and sterilize all suction equipment before shipment or service to ensure transportation personnel and/or service personnel are not exposed to any hazardous contamination.

Clean and sterilize all suction equipment if contaminated before disassembly, to ensure service personnel are not exposed to hazardous contamination.

Following sterilization with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the material. Aerate parts for 8 hours at 130ºF (54ºC).

If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure (Section 8 Service Checkout Procedure) must be performed before using the equipment on the patient.

The low vacuum limit setting procedure (Section 7.3 Suction Level Limit Setting - Low Models ONLY) must be followed when repairing low vacuum regulators. Failure to do this may result in suction exceeding the prescribed level.

1.3 Cautions

Do not lubricate any internal components of the regulator module.

Do not use any Loctite® products to seal the fitting and adapter port threads (or products which contain methacrylate ester as an active ingredient).

Only competent individuals trained in the repair of this equipment should attempt to service it.

To help prevent aspirate from entering the regulator, wall outlet and pipeline equipment, an overflow safety trap and suction filter should be attached prior to its use. Aspirate in the regulator will impair the operation. The use of the overflow safety trap and suction filter will help prevent this and extend the life of the suction equipment.

Use of lubricants other than recommended may degrade plastic or rubber components.

Prior to placing the unit back into service after repair or disassembly, perform the service checkout procedure (Section 8 Service Checkout Procedure).

Not for Field or Transport use**

1.4 Intended Use

The vacuum regulator is intended to be used in the medical facility as a means to evacuate media (i.e. fluids) from the body.

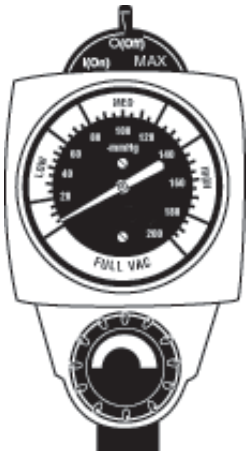
** The categories of Field and Transport Use are specifically defined in ISO® 10079-3, “Field” means use at accidents or emergencies outside a hospital. “Transport” means use in ambulances, cards and airplanes. These situations may expose the equipment to uneven support, water, dirt mechanical shock and temperature extremes. Ohio Medical suction equipment has not been tested to comply with the specific requirements of these categories.

2/Scope

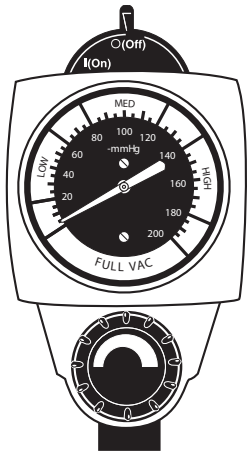
This service manual contains service, maintenance and parts information on all models of the Continuous Vacuum Regulator.

2.1 North American Vacuum Regulators.

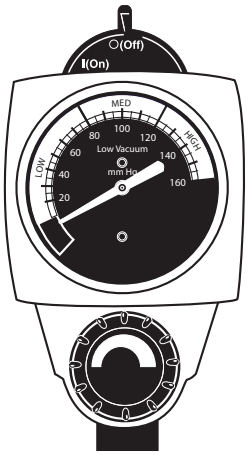
Note: Part numbers given are for vacuum regulators without fittings or adapters.



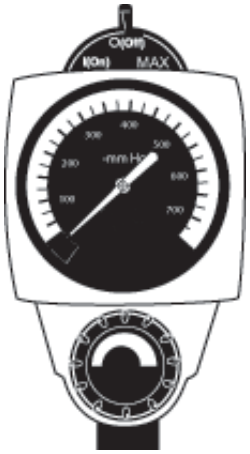
Standard Three Mode Continuous
6700-1224-900
0-200 mmHg-FULL VAC



Standard Two Mode Continuous
6700-1225-900
0-200 mmHg-FULL VAC



Low Continuous
6700-1227-900
0-135 mmHg

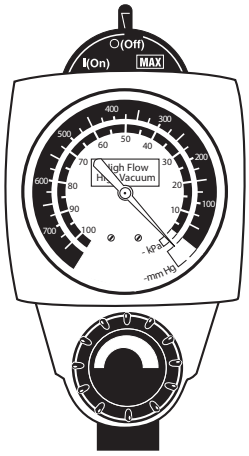


High Three Mode Continuous
6700-1226-900
0-760 mmHg

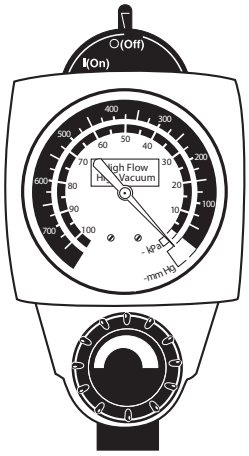
2.2 International Vacuum Regulators

Important: International vacuum regulators comply with the requirements of ISO® 10079-3 and are CE marked.

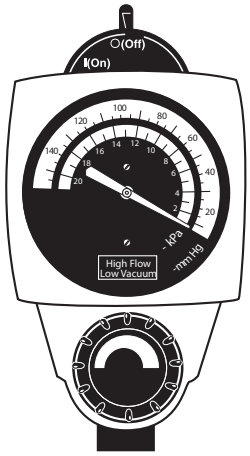
Note: Part numbers given are for vacuum regulators without fittings or adapters.



Three Mode High Continuous
6700-1229-900
CCW
0-760 mmHg (0-101.3 kPa)



Two Mode High Continuous
6700-1230-900
CCW
0-760 mmHg (0-101.3 kPa)



Two Mode Low Continuous
6700-1233-900
CCW
0-135 mmHg (0-18.0 kPa)

3.1 Description

WARNING

⚠ **Do not use this device in the presence of flammable anesthetics. Static charges may not dissipate and a possible explosion hazard exists in the presence of these agents.**

The Continuous Vacuum Regulator is a lightweight, compact unit used throughout the hospital primarily for pharyngeal/tracheal suctioning (airway management). Various models provide regulated or full-line vacuum for hospital suction procedures.

There are several models of the Continuous Vacuum Regulators. All models contain a vacuum gauge which indicates suction supplied by the regulator. Each has a positive pressure safety relief valve to prevent pressurization by either failed injector vacuum (Venturi) units or inadvertent cross connection to pressurized gasses. In addition, the Low Continuous models include a vacuum relief valve to limit maximum suction.

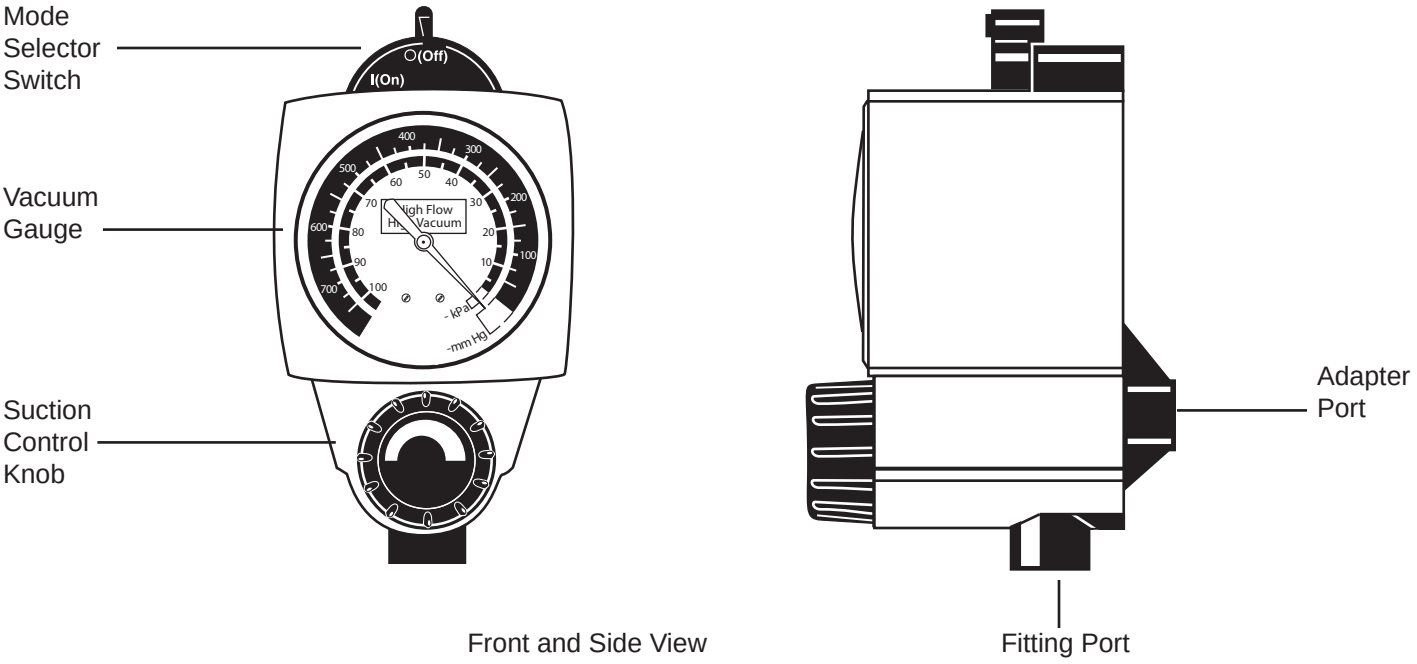
Some models operate in a regulated or non-regulated (MAX) mode. Others operate only in the regulated (limited) mode.

In the non-regulated (MAX) mode, the vacuum source is routed directly to the fitting port. The regulator module is bypassed and full-line vacuum is provided.

In the regulated (limited) mode, the vacuum source is connected through the regulator module which functions as an automatic valve. Turning the suction control knob adjusts the position of the regulator module and allows selection of a predetermined level of suction when set according to instructions.

During use, as the flow requirement increases, the valve automatically opens to maintain suction at the pre-set level. When the flow requirement decreases, the valve automatically closes to maintain suction at the preset level. The same mechanism compensates for changes in supply vacuum and automatically maintains the pre-set suction level when set according to instructions.

1. Suction Control Knob - Allows adjustment of suction to the patient.
2. Mode Selector Switch - Allows quick mode changes.
   a. | (On) - Suction can be adjusted with the suction control knob.
   b. O (Off) - No suction is supplied to the patient.
   c. MAX - Maximum full-line vacuum is supplied to the patient.
3. Vacuum Gauge - The suction level to the patient is displayed during use.



Front and Side View

3.2 Specifications

Gauge:	Accuracy: ±5% of full scale deflection
Flow Rate:	0 to 80 LPM without fittings at full increase setting depending on supply vacuum and open air flow
Positive Pressure Safety Relief Valve:	Located in the vacuum supply line to prevent pressurization of the patient connection by failed injector vacuum (Venturi) units, or inadvertent cross connection to pressurized gases

Ranges:	Gauge Range	Regulated Suction*
Standard Models	0 to 200 mmHg (0 to 26.7 kPa)	0 to 760 mmHg (0 to 101.3 kPa)
High Models	0 to 760 mmHg (0 to 101.3 kPa)	0 to 760 mmHg (0 to 101.3 kPa)
Low Models	0 to 160 mmHg (0 to 21.3 kPa)	0 to 135 mmHg (0 to 18.0 kPa)

* When measured with an independent measuring device.

Vacuum Relief Valve: (Low Vacuum models ONLY)	135 mmHg ± 5 mmHg (18.0 kPa ± 0.7 kPa)
Weight: (Less fittings)	11 oz (312 grams)
Weight Low Vacuum models: (Less fittings)	12 oz (340 grams)
Dimensions: (Less fittings)	Height: 5.7 in (145 mm) Width: 3.0 in (76 mm) Depth: 3.8 in (96 mm)
Latex tubing, 0.25 in (6.4 mm) ID X 12 in (30 cm) supplied:	0 to full vacuum Flow dependent on source and setup
Disposable tubing (Available separate in some markets; 6 mm ID X 450 mm, 750 mm and 2M) to connect regulator and collection bottle	0 to full vacuum Flow dependent on source and setup
Disposable Suction Filter:	0 to full vacuum 0 to 100 LPM @ 650 mmHg (87 kPa)

Environmental Specifications

Operating Temperature Range:	40ºF to 120ºF (4ºC to 49ºC)
Storage Temperature Range:	0ºF to 150ºF (-18ºC to 71ºC)
Operating and Storage Relative Humidity:	5 to 95%

4.1 Equipment Set-up

Insert the probe into the vacuum wall outlet. If the regulator is mounted elsewhere, connect a vacuum supply hose between the regulator's probe adapter and the wall outlet.

WARNINGS

⚠ **Connect the vacuum regulator to the vacuum source only and check its operation before attaching the patient connection.**

⚠ **Connection to pressure sources, even momentarily, could injure the patient or operator.**

CAUTION

⚠ Connection to pressure sources, even momentarily, could damage the equipment.

Note: For proper installation of adapters/probes and fittings see Appendix A-1.

Connect the collection bottle's vacuum port to the regulator's fitting port or overflow safety trap with the appropriate suction filter and vacuum tubing.

Use hospital-supplied suction tubing between the end piece and the collection container and between the patient port and the patient (minimum inside diameter is 0.25 in [6 mm]).

ISO 10079-3 (section 5.1.2) states that "the usable volume of the collection container shall not be less than 500 mL."

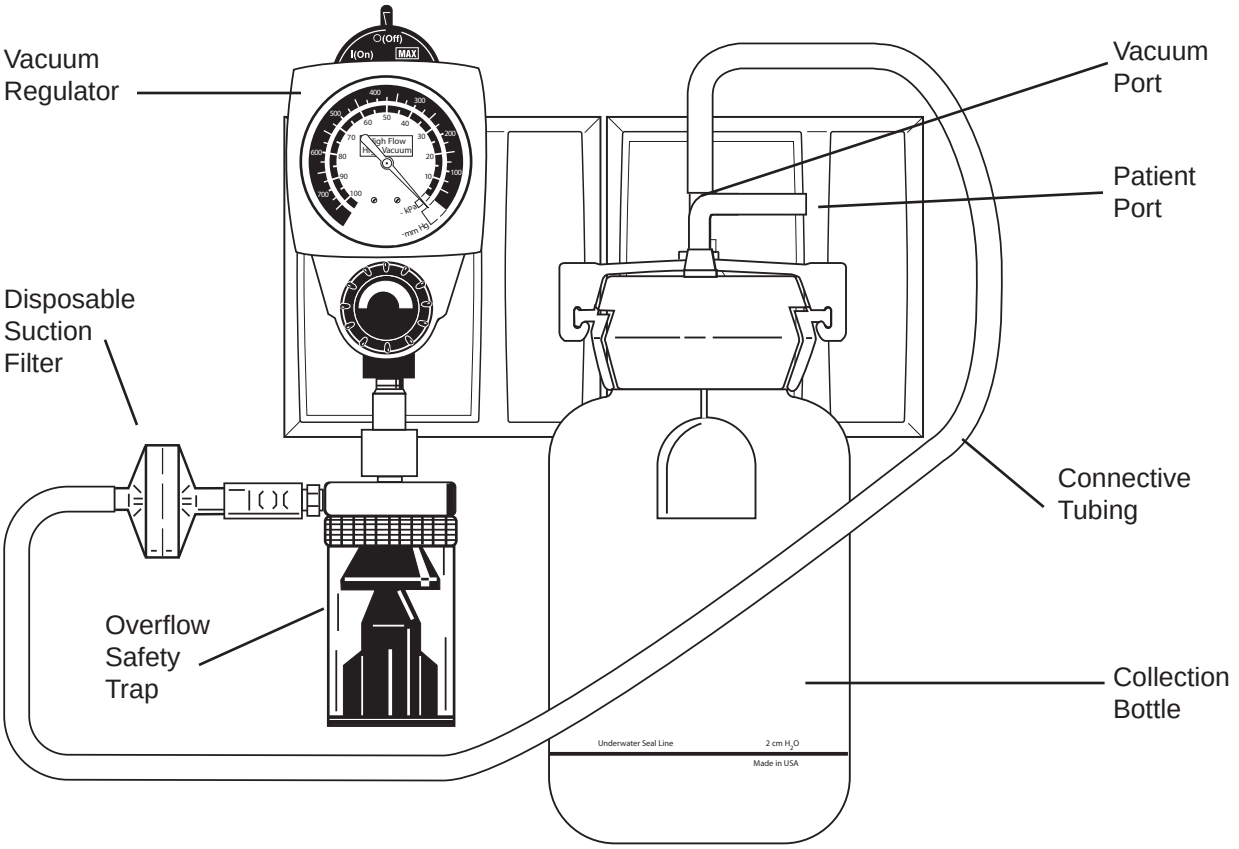
An Ohio Medical high flow suction filter should be used between the collection container and regulator to prevent contamination of the regulator. Hospital-supplied suction tubing must be used between the catheter and the collection bottle. Recommended minimum inside diameter is 0.25 in (6 mm).

High Flow Suction Filters
Hydrophilic

Pkg of 20	6730-0350-800
Pkg of 200	6730-0351-800

Hydrophobic

	Tubing x tubing nipple	1/8" NPT x tubing nipple
Pkg of 3	6730-0570-800	6730-0580-800
Pkg of 10	6730-0571-800	6730-0581-800
Pkg of 100	6730-0572-900	6730-0582-800



Equipment Set-Up

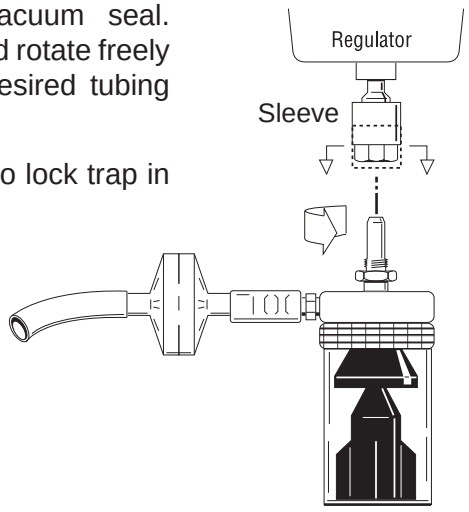
4.2 Attaching the Overflow Safety Trap (OST)

CAUTION

⚠ To help prevent aspirate from entering the regulator, wall outlet and pipeline system, an overflow safety trap should be attached prior to its use. Aspirate in the regulator, wall outlet and pipeline system may impair their operation. The use of the overflow safety trap and suction filter will help prevent this and extend the life of suction equipment.

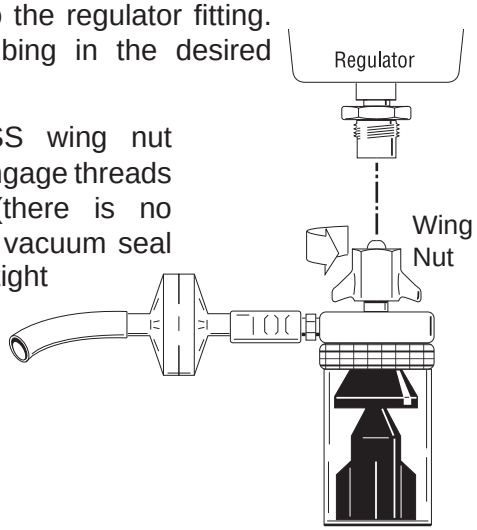
Standard fitting

1. Raise the sleeve and insert the trap into the regulator fitting.
2. Turn the trap clockwise about one and a half turns to engage the threads. The trap does not need to be screwed tight; an O-ring in the regulator fitting provides a vacuum seal. The trap should rotate freely to allow the desired tubing positioning.
3. Lower sleeve to lock trap in position.



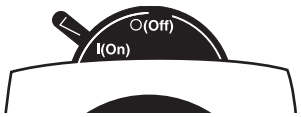
DISS fitting

1. Insert trap into the regulator fitting. Situate the tubing in the desired position.
2. Turn the DISS wing nut clockwise to engage threads and tighten (there is no O-ring, so the vacuum seal depends on a tight connection).

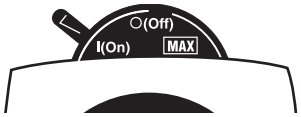


4.3 Mode Selection

| (On) - Suction can be adjusted with the suction control knob.

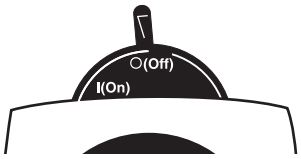


2-Mode Switch

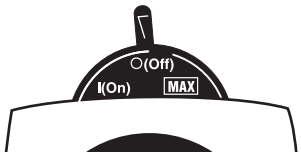


3-Mode Switch
| (On)

O (Off) - No suction is supplied to the patient.

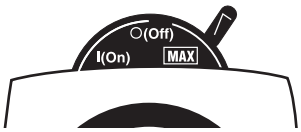


2-Mode Switch



3-Mode Switch
O (Off)

MAX - Maximum, full-line vacuum is supplied to the patient.

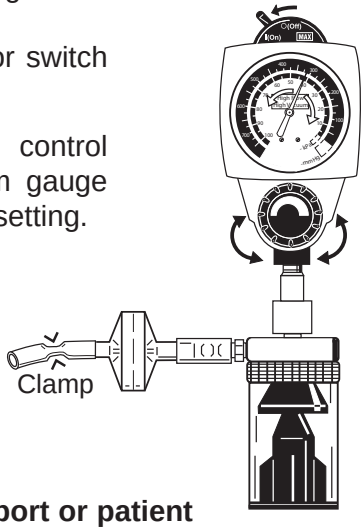


3-Mode Switch
MAX

Note: Available on three mode vacuum regulators only.

4.4 Setting the Suction Level

1. Occlude or clamp tubing.
2. Turn the mode selector switch to | (On).
3. Rotate the suction control knob until the vacuum gauge indicates the required setting.



WARNING

⚠ **The regulator fitting port or patient connector must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction.**

4.5 Pre-Use Checkout Procedure

WARNINGS

⚠ **The pre-use checkout procedure must be performed before using the equipment on each patient. If the regulator fails any part of the pre-use checkout procedure, it must be removed from service and repaired by qualified service personnel.**

⚠ **Connect the vacuum regulator to the vacuum source only and check it's operation before attaching the patient connection.**

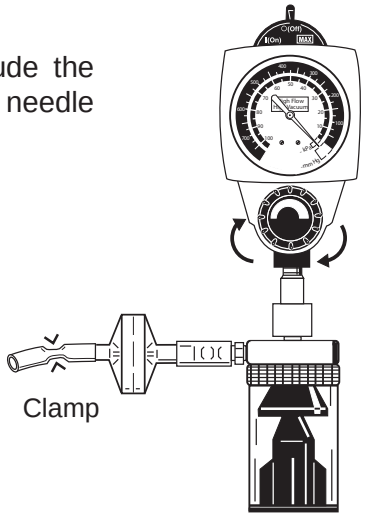
⚠ **Connection to pressure sources, even momentarily, could injure the patient or operator.**

CAUTION

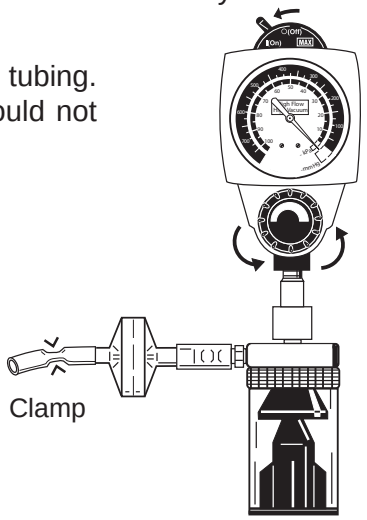
⚠ Connection to pressure sources, even momentarily, could damage the equipment.

All tests must be performed with a supply vacuum of 500 mmHg (66.7 kPa) minimum.

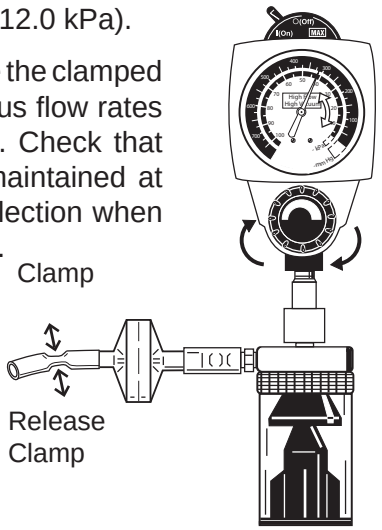
1. Turn the mode selector switch to O (Off).
2. Rotate the suction control knob one full turn clockwise (increase).
3. Clamp tubing to occlude the fitting port. The gauge needle should not move.



4. Turn the mode selector switch to | (On).
5. Rotate the suction control knob fully counter-clockwise (decrease).
6. Clamp the connective tubing. The gauge needle should not move.

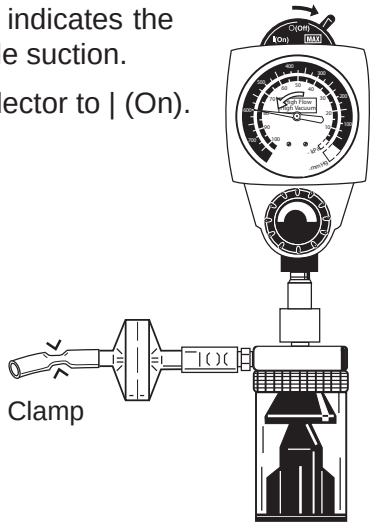


7. With the connective tubing clamped, increase the suction to 90 mmHg (12.0 kPa).
8. Slowly open and close the clamped tubing to create various flow rates through the regulator. Check that the suction level is maintained at ± 5% of full scale deflection when the tubing is clamped.



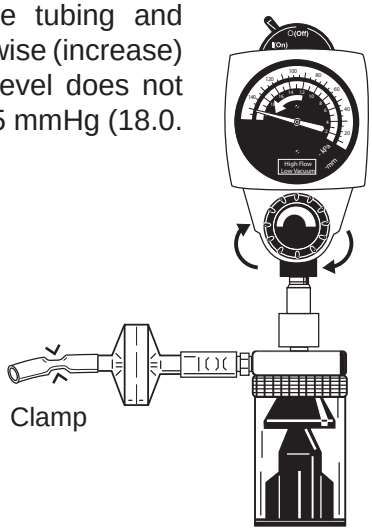
For Standard Two Mode Continuous, go to step 11.

9. High and Standard Three Mode Continuous ONLY
   a. Turn the mode selector to MAX.
   b. Clamp the connective tubing and check that the gauge needle indicates the maximum available suction.
   c. Turn the mode selector to | (On).

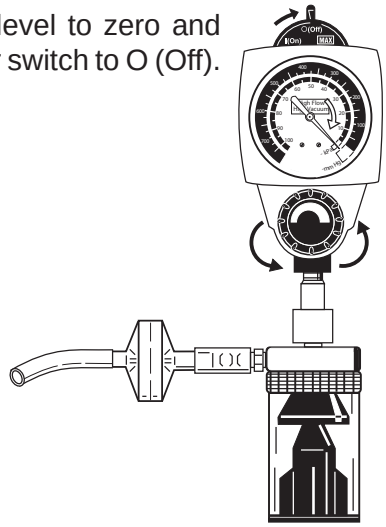


10. Low Continuous ONLY

    Clamp the connective tubing and rotate knob fully clockwise (increase) to verify the suction level does not exceed 135 mmHg ± 5 mmHg (18.0. kPa ± 0.7 kPa).



11. Reduce the suction level to zero and set the mode selector switch to O (Off).

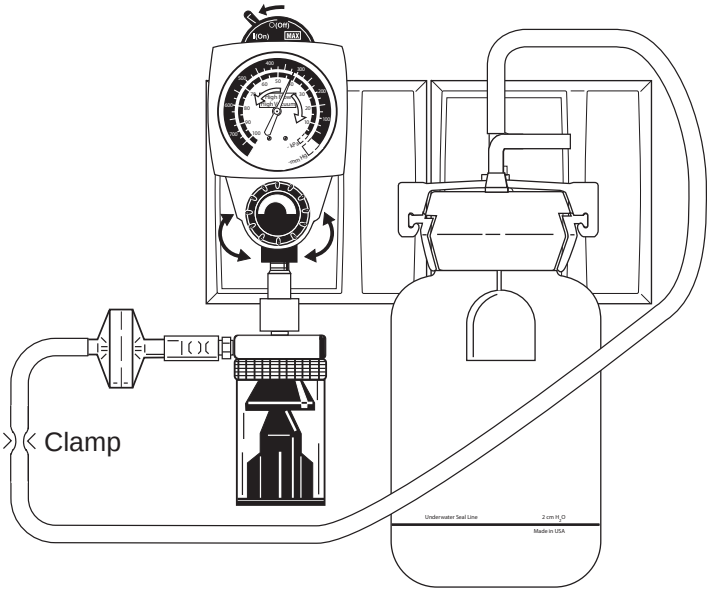


4.6 Patient Setup

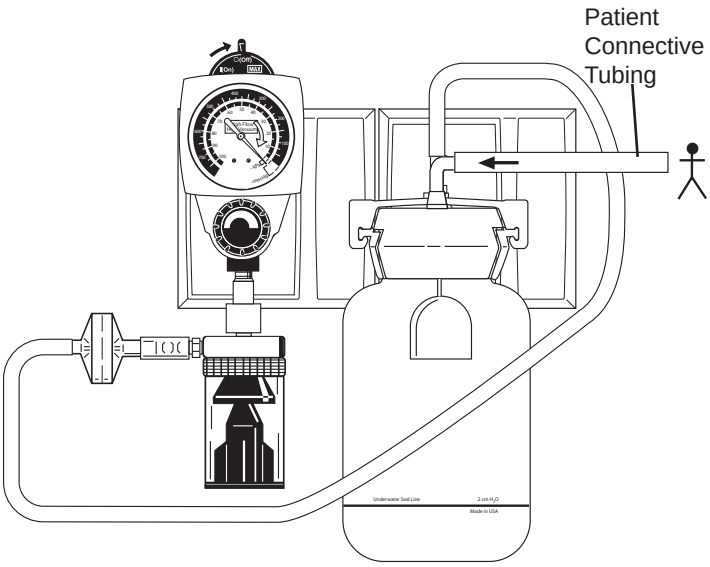
1. Make sure the pre-use checkout procedure (Section 4.5 Pre-Use Checkout Procedure) has been performed.
2. Clamp the connective tubing and turn the mode selector switch to | (On).
3. Set the prescribed suction level.

WARNING

⚠ **The regulator must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction.**

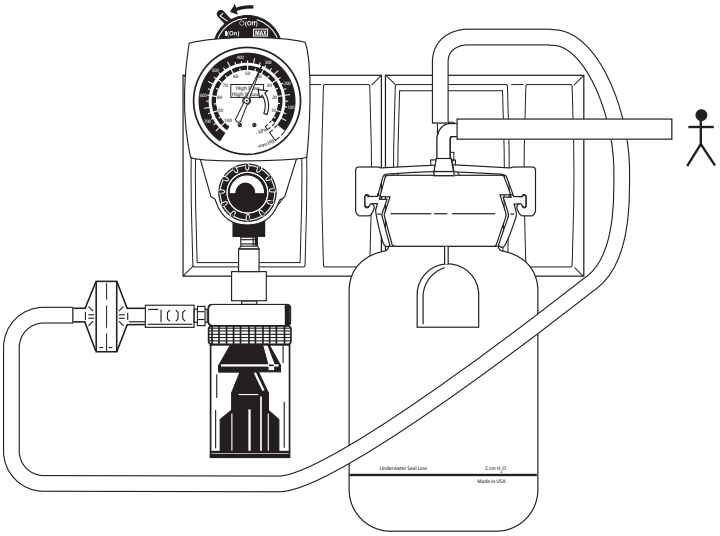


4. Turn the mode selector switch to O (Off).
5. Attach the connective tubing to the vacuum port of the collection container.



6. Turn the mode selector switch to | (On).

Important: The Low models do not deliver suction in excess of 135 mmHg ± 5 mmHg (18.0. kPa ± 0.7 kPa).



5.1 Cleaning

WARNING

⚠ **After patient use, regulators may be contaminated. Handle in accordance with your hospital's infection control policy.**

5.1.1 Routine Exterior Cleaning

Routine cleaning of the regulator is recommended as a standard procedure after each use.

Wipe all exterior surfaces with a solution of water and mild detergent.

5.1.2 Internal Component Cleaning

CAUTION

⚠ Cleaning the gauge may result in damage.

The regulator requires cleaning if it becomes flooded with patient fluid as a result of misuse.

1. Refer to the Section 8 Service - Disassembly and Assembly instructions.
2. All internal components, with the exception of the gauge, may be cleaned with a solution of warm water and mild detergent, preferably an enzymatic cleaner.
3. Dry all components with a lint free cloth before assembly.

5.2 Sterilization

Should misuse occur, resulting in accidental flooding of the regulator, the regulator may be sterilized using ethylene oxide (ETO). After sterilization, follow the service checkout procedures in Section 8.

WARNING

⚠ **Following sterilization with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the material. Aerate parts for 8 hours at 130°F (54°C).**

CAUTIONS

⚠ Do not steam autoclave or liquid sterilize the Continuous Vacuum Regulator. Severe impairment to the operation of the regulator will result. The only acceptable method of sterilization is with gas (ethylene oxide).

⚠ Sterilization with ethylene oxide mixtures may cause crazing (minute superficial cracking) of some plastic parts. Crazing will be more pronounced when mixtures containing Freon® are used.

Note: The vacuum regulator should only be sterilized if it is contaminated or maintenance is to be performed.

1. The regulator should be sterilized with the mode selector switch in the | (On) position.
2. The only acceptable method of sterilization is with ethylene oxide. Ethylene oxide mixtures can be used at temperatures of 125° to 135°F (52° to 57 °C). If this temperature cannot be obtained, room temperature sterilization with 100% ethylene oxide can also be used. Sterilization is not recommended as a standard procedure after each use.
3. After each sterilization, check the condition of the internal filter. If the filter appears to have shrunk, replace it before placing the regulator back in service.
4. Adequately aerate the regulator prior to disassembly, shipment or use. Aerate parts prior to reassembly.

6/Troubleshooting

	Problem		Possible Causes		Remedy
A.	No gauge indication and no suction in any setting	1. 2. 3. 4. 5. 6. 7.	No supply vacuum Kinked tube Poor connection Blocked adapter port Blocked backplate Blocked adapter Blocked wall outlet	1. 2. 3. 4. 5. 6. 7.	Correct supply problems Straighten tube Check all connections and seals Unblock port Clean with soap and water and pipe cleaner Replace adapter Unblock outlet
B.	No gauge indication but suction is being delivered	1. 2. 3.	Blocked gauge pressure sensing orifice Gauge mechanism locked by debris Gauge mechanism damaged	1. 2. 3.	Clean or replace gauge Clean or replace gauge Replace gauge
C.	Gauge indication but no suction is being delivered	1. 2. 3. 4.	Blocked fitting port Overflow Safety Trap shut-off Blocked external filter Blocked fitting	1. 2. 3. 4.	Clean port Reset flow and/or empty trap Replace filter Clean fitting
D.	Suction level cannot be adjusted	1. 2. 3. 4.	Mode selector switch in MAX position Regulator module small O-ring failure Regulator module diaphragm rupture Regulator module stem screw loose	1. 2. 3. 4.	Switch to I(On) Replace rubber components with regulator module replacement kit Replace rubber components with regulator module replacement kit Tighten stem screw
E.	Insufficient flow through regulator	1. 2.	Partial blockage in wall supply Partial blockage in regulator	1. 2.	Remedy: i. Confirm wall supply open air flow meets minimum hospital requirements ii. Unblock if necessary Remedy: i. Perform the flow test (Section 8.2 Flow Test) ii. Clear blockage if necessary
F.	Inaccurate gauge reading Note: All gauge needles should come to rest within the zero range bracket or return to the stop pin when no suction is being supplied.	1.	Damaged gauge	1.	Replace gauge
G.	With the fitting port occluded, unable to decrease the suction level and gauge needle does not return to zero when switched to O (Off)	1. 2.	Blocked filter and/or orifice Damaged gauge	1. 2.	Clear orifice and replace filter Replace gauge
H.	No suction in any setting and whistling noise from inside the regulator	1. 2.	Positive pressure safety relief valve failure Vacuum relief valve failure (low models ONLY)	1. 2.	Replace positive pressure safety relief valve Replace O-ring and ensure that the steel ball is present and clean

7.1 Service Tools and Equipment

CAUTION

⚠ Use of lubricants other than recommended may degrade plastic or rubber components.

The following items should be on hand during any service procedure.

- Supply vacuum: 500 mmHg ± 10 mmHg (66.7 kPa ± 1.3 kPa) & 50 LPM open air flow minimum
- Supply vacuum regulator with gauge, 760 mmHg (101.3 kPa) Full Scale.
- Low vacuum calibration gauge, 225 mmHg (30 kPa) full scale* (Ohio Medical P/N 6700-0353-800)
- High vacuum calibration gauge, 760 mmHg (101.3 kPa) Full Scale*(Ohio Medical P/N 6700-0352-800)
- 50 LPM flowmeter (Ohio Medical P/N 6700-0355-800)
- Hexagonal allen wrench 3/32”
- Phillips head screwdriver, No. 2
- Flat head screwdriver, 1/4”
- Pliers
- Dow Corning® 111 grease (Ohio Medical P/N 6700-0074-200)
- Loctite® 242 removable thread locker (Ohio Medical P/N 0220-5016-300)
- Tubing clamp
- Bubble leak tester
- Tweezers (filter remover)
- Wooden tooth pick (O-ring remover)
- Pipe cleaner

(*) Accuracy: ±1% of full scale deflection

7.2 Continuous Vacuum Regulators (All Models)

7.2.1 Disassembly

WARNINGS

⚠ **If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure (Section 8 Service Checkout Procedure) must be performed before using the equipment on a patient.**

⚠ **Clean and sterilize all suction equipment if contaminated before disassembly, to ensure service personnel are not exposed to hazardous contamination.**

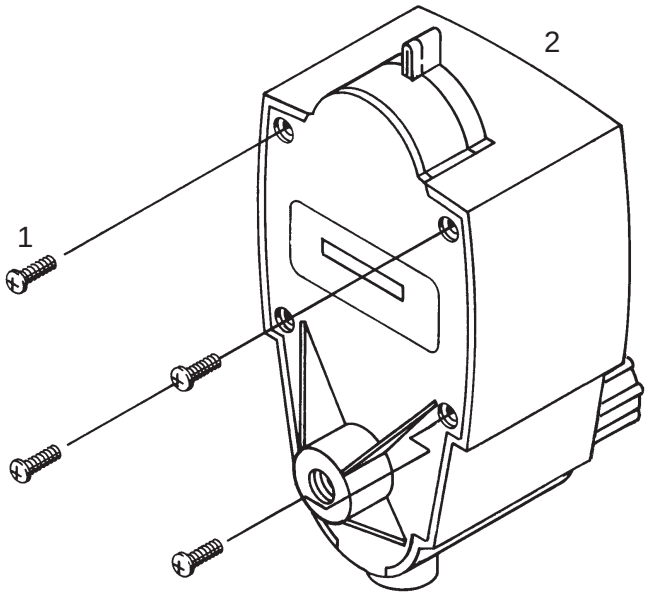
⚠ **If repairing or replacing a regulator module on a Low Vacuum Regulator, you must perform the suction level limit setting procedure (Section 7.3 Suction Level Limit Setting - Low Models ONLY). Failure to do this may result in suction exceeding the prescribed level.**

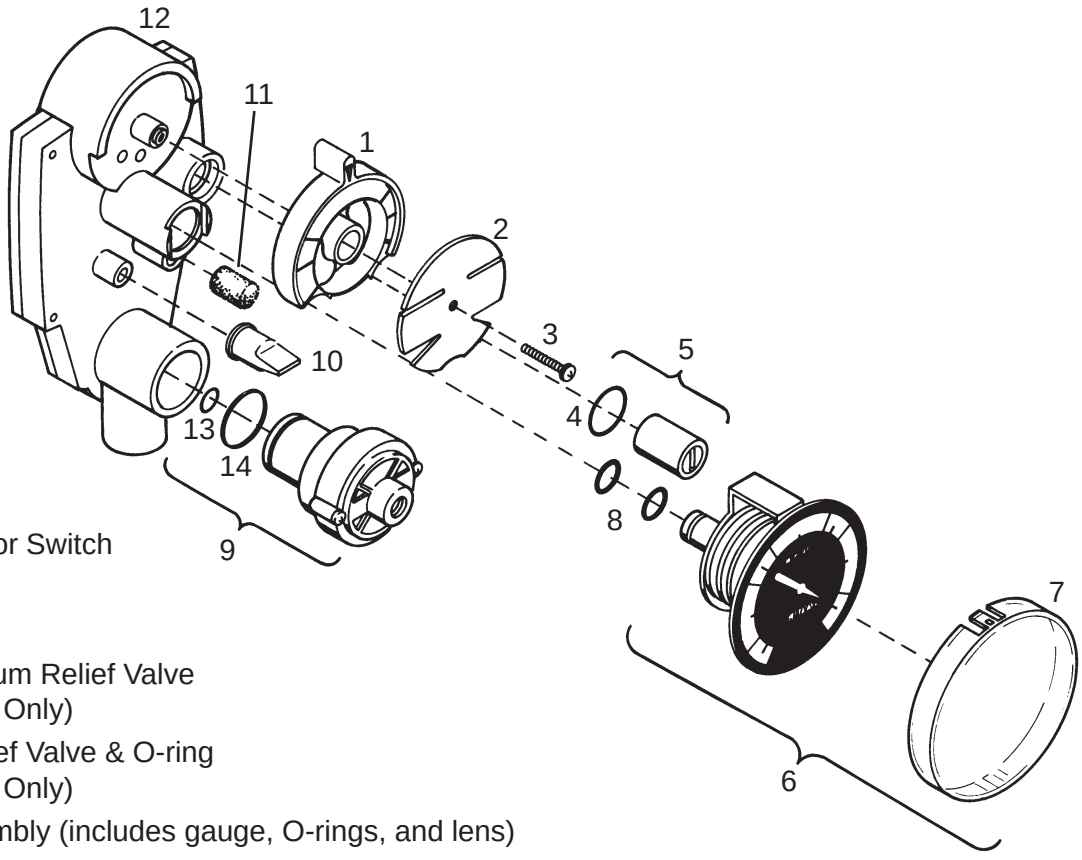
CAUTION

⚠ The gauge assembly must be handled with utmost care to retain its precision. If the lens is removed, do not rest the gauge on its face.

7/Service - Disassembly and Assembly

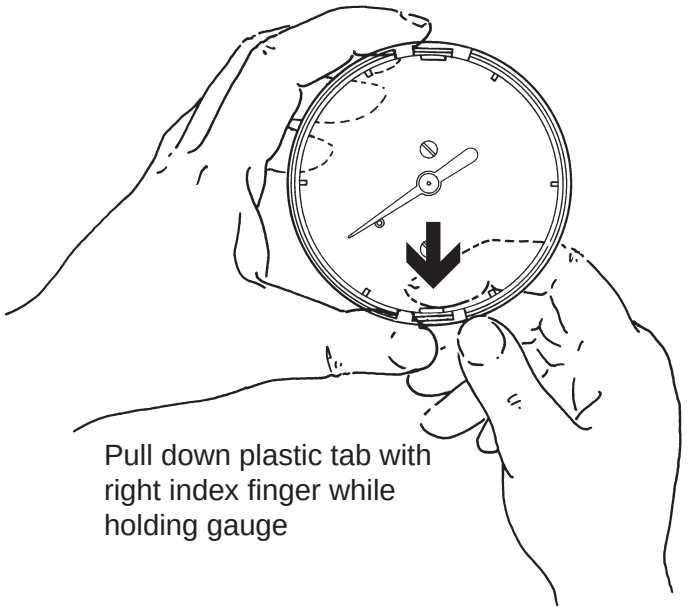
1. Cover Screw (4)
2. Cover Assembly





1. Mode Selector Switch
2. Switch Plate
3. Screw
4. O-ring, Vacuum Relief Valve (Low Models Only)
5. Vacuum Relief Valve & O-ring (Low Models Only)
6. Gauge Assembly (includes gauge, O-rings, and lens)
7. Lens
8. O-ring (2), Gauge
9. Regulator Module
10. Positive Pressure Safety Relief Valve
11. Filter (Internal)
12. Base
13. O-ring, Stem
14. O-ring, Regulator Module

1. Remove the four cover screws from the back of the regulator.
2. Carefully pull the cover assembly off the back body.
3. To remove the gauge assembly, grasp the assembly and pull straight out. The snap-fit lens can also be removed (if applicable) for replacement.



Snap Fit Lens Removal

4. To remove the regulator module from the cover assembly, rotate the suction control knob counter-clockwise until the regulator module is free.
5. Using tweezers, remove the filter. Replace with a new filter.
6. Grasp the positive pressure safety relief valve and pull it from the back body.
7. Remove the mounting screw from the switch plate assembly and remove the switch plate and mode switch.
8. Low models ONLY: Grasp the vacuum relief valve and pull it from the back body.

7.2.2 Assembly

CAUTION

⚠ To prevent stripping the plastic threads, place the screw in the hole and turn counter-clockwise until it drops into the original thread, then tighten the screw.

1. Place the positive pressure safety relief valve in position and push onto the back body.
2. Low models ONLY: Lubricate the vacuum relief valve O-ring and install it in the valve housing.
3. Lubricate the switch gasket surface with a thin coating of Dow Corning® 111 grease.
4. Place the mode switch on the base with the arrow at 12 o'clock.
5. Place the switch plate onto the switch so that the O (Off) is under the arrow. Install and tighten the mounting screw.
6. Test the mode switch at all positions.
7. Place the internal filter into the proper cavity and push until it hits the bottom of the base.
8. Place the regulator module into the cover with the screw thread facing the knob. Align the protruding ears at 3 and 9 o'clock and rotate the suction control knob clockwise until the threads engage.
9. Install the snap-fit lens by placing one of the retaining tabs over the edge of the gauge face, and then press lightly until the other tab snaps onto the gauge face. Rotate the lens to confirm proper installation.
10. Install the gauge assembly by lubricating the gauge O-rings with a thin coating of Dow Corning® 111 grease and push the gauge into the base mount. Ensure that the gauge is properly aligned.
11. Place the cover assembly onto the base and push together until the base and back of the cover are flush.
12. Install the 4 cover screws.

7.3 Suction Level Limit Setting - Low Models ONLY

WARNING

⚠ **This low vacuum limit setting procedure must be followed when repairing Low Vacuum Regulators. Failure to do this may result in suction exceeding the prescribed level.**

1. Remove the cover.
2. Connect the supply vacuum to the adapter port.
3. Turn the mode selector switch to | (On).
4. Occlude the fitting port.
5. Slowly pull the regulator module away from the base. Note the suction level at which the relief valve opens. The relief valve should open at 135 mmHg ± 5 mmHg (18.0. kPa ± 0.7 kPa).
6. If adjustment is required, grip the vacuum relief valve firmly with pliers and rotate the screw about 1/8 turn with a screwdriver. Repeat the previous step and check the suction level at which the valve opens.

   Note: Clockwise rotation will increase the suction level at which the relief valve opens. Counter-clockwise rotation will decrease it.

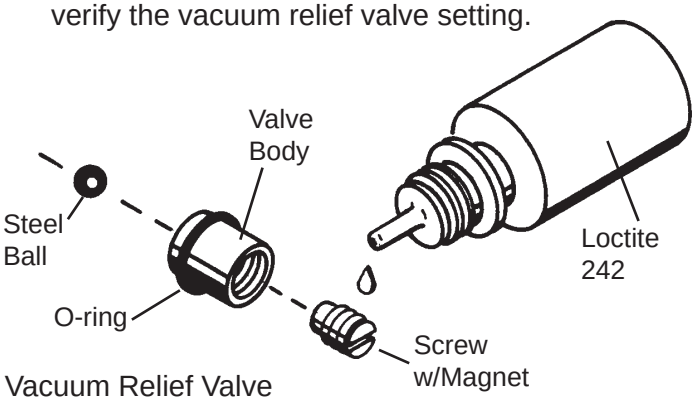
WARNING

⚠ **Excess Loctite® may seal the steel ball to the seat. This will disable the vacuum relief valve and may allow suction to exceed the preset limit.**

CAUTION

⚠ When Loctite is used on the vacuum relief safety valve, ensure that it only contacts the metal parts. Loctite causes many plastic parts to deteriorate.

7. Lock the adjusting screw with a drop of removable thread locker such as Loctite 242. Repeat step 5 to verify the vacuum relief valve setting.



Vacuum Relief Valve

7.4 Regulator Module

WARNING

⚠ **If repairing or replacing a regulator module on a Low Vacuum Regulator, you must perform the suction level limit setting procedure (Section 7.3 Suction Level Limit Setting - Low Models ONLY). Failure to do this may result in suction exceeding the prescribed level.**

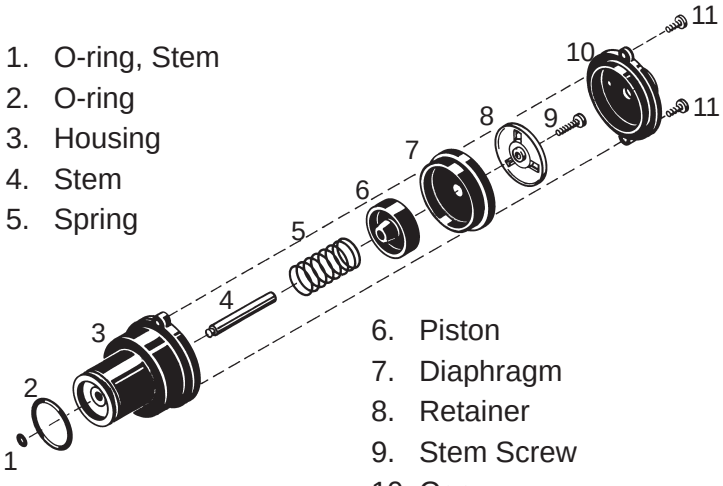
CAUTIONS

⚠ Do not lubricate any internal components of the regulator module.

⚠ The cap screws can strip the regulator module housing threads if they are screwed in too tight.

7.4.1 Disassembly

1. Remove the cap screws (2) and remove the cap.
2. Remove the O-rings (2).
3. Observe the position of the diaphragm convolution to aid in assembly.
4. Withdraw the diaphragm/stem assembly from the housing.
5. Remove the spring.
6. Grasp the stem with your fingers and unscrew the stem screw.
7. Remove the retainer, diaphragm and piston from the stem.

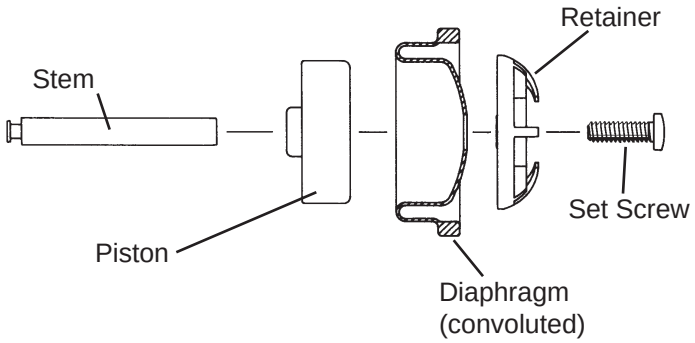


1. O-ring, Stem
2. O-ring
3. Housing
4. Stem
5. Spring
6. Piston
7. Diaphragm
8. Retainer
9. Stem Screw
10. Cap
11. Cap Screw

Regulator Module Parts and Descriptions

7.4.2 Assembly

1. Return the diaphragm to its original position (convoluted), with the molded number facing the retainer.
2. Assemble the diaphragm onto the retainer by lining up their center holes as shown in the diagram.
3. Insert the piston into the diaphragm and ensure that the retainer mates with the recess in the piston.
4. Insert the stem through the piston.
5. Holding the retainer/diaphragm/piston/stem as an assembly with your fingers, insert the stem screw and tighten.
6. Place the spring in the housing.
7. Insert the retainer/diaphragm/piston/stem assembly through the spring and into the cavity in the housing. Fit the diaphragm bead into the groove in the housing.
8. Install the cap and the two cap screws.
9. Apply a small amount of Dow Corning® 111 grease to the O-rings only.
10. Install O-rings onto the stem and housing.



Diaphragm Assembly

8/Service Checkout Procedure

WARNING

⚠ **If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure (Section 8 Service Checkout Procedure) must be performed before using the equipment on a patient.**

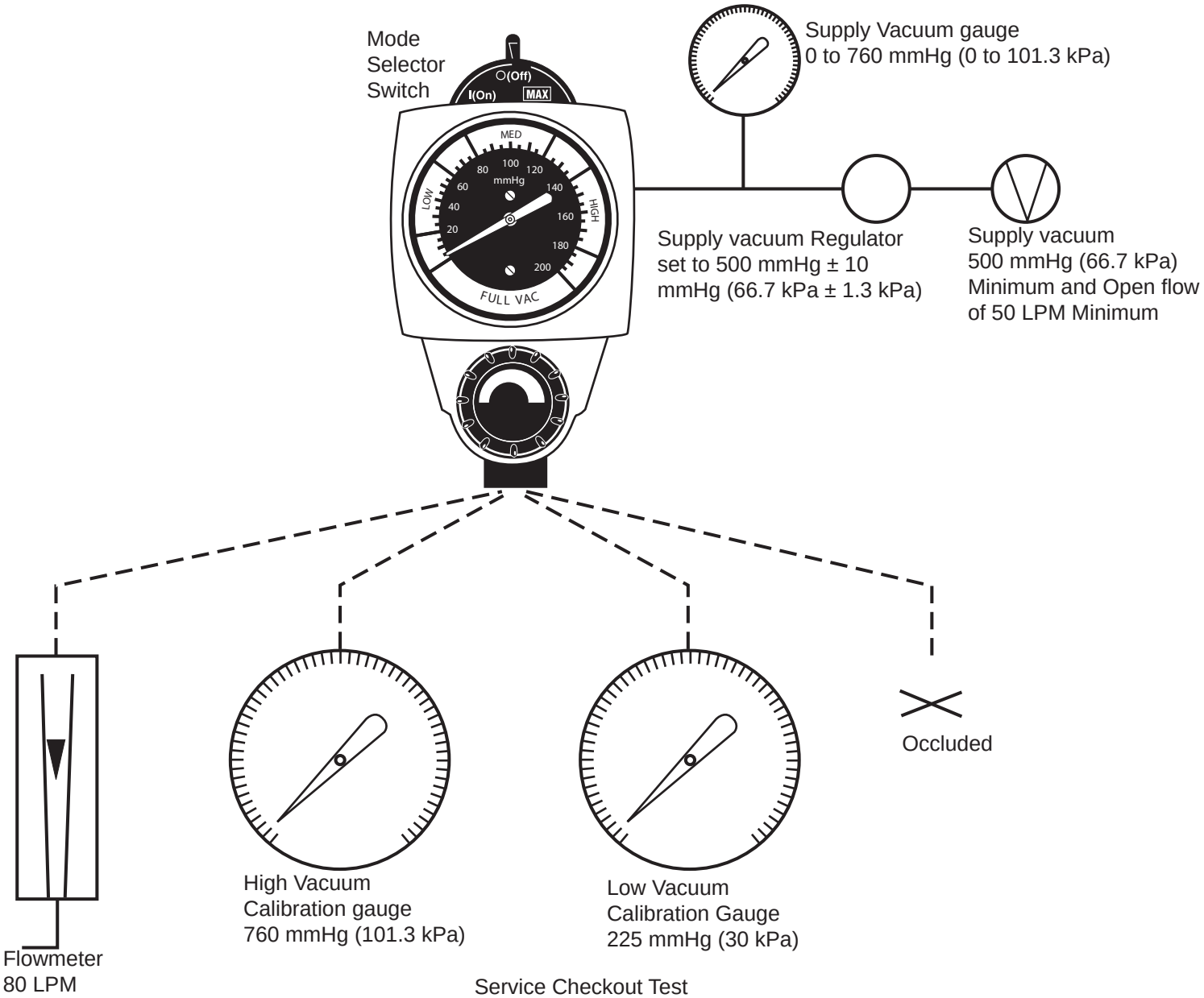
Important: This entire service checkout procedure must be performed in numerical order.

8.1 Set-up

1. Verify that there is 500 mmHg ± 10 mmHg (66.7 kPa ± 1.3 kPa) vacuum on the supply gauge.
2. The supply open flow must be 50 LPM minimum.
3. Connect the supply vacuum to the adapter port.

8.2 Flow Test

1. Connect the regulator's fitting port to the flowmeter with tubing.
2. Rotate the suction control knob fully clockwise (increase).
3. Turn the mode selector switch to | (On) and verify that the flow rate exceeds 30 LPM.
4. Three Mode ONLY: Turn the mode selector switch to MAX and verify that the flow rate exceeds 30 LPM.
5. Turn the mode selector switch to O (Off).
6. Disconnect the flowmeter.



Service Checkout Test

8.3 Gauge Test

Note: All Ohio Medical gauges are supplied with an accuracy of ± 5% of full scale deflection throughout their range. The table below is provided for reference.

Gauge	Range	Tolerance
Standard Models	0 to 200 mmHg (0 to 26.7 kPa)	± 10 mmHg (1.3 kPa)
High Models	0 to 760 mmHg (0 to 101.3 kPa)	± 38 mmHg (5.1 kPa)
Low Models	0 to 160 mmHg (0 to 21.3 kPa)	± 8 mmHg (1.1 kPa)

Note: All gauge needles should come to rest within the zero range bracket or return to the stop pin when no suction is being supplied. Gauges which do not comply may be out of calibration.

When checking gauge accuracy, be sure that the calibration gauge has an accuracy of 1% of full scale deflection or better.

8.3.1 High Vacuum Gauges ONLY

1. Connect the regulator's fitting port to the high calibration gauge with tubing.
2. Turn the mode selector switch to | (On).
3. Ensure that the gauge is in agreement with the high vacuum calibration gauge within the ± 38 mmHg (± 5.1 kPa) tolerance. Recommended test points are 100, 300, and 450 mmHg (13.3, 40.0, and 60.0 kPa).

8.3.2 Standard and Low Vacuum Gauges ONLY

1. Connect the regulator's fitting port to the low calibration gauge with tubing.
2. Turn the mode selector switch to | (On).
3. Ensure that the gauge is in agreement with the low vacuum calibration gauge within the ± 10 mmHg (± 1.3 kPa) or the ± 8 mmHg (± 1.1 kPa) tolerance for standard and low gauges respectively. Recommended test points are 40 and 80 mmHg (5.3 and 10.7 kPa) for the standard and low models and 140 mmHg (18.7 kPa) for standard model only.
4. For the standard gauge ONLY: Rotate the suction control knob fully clockwise (increase) and verify its reading is in the FULL VAC range.

8.4 Regulation Test

1. Disconnect the calibration gauge and occlude the fitting port.
2. If using a High Vacuum Regulator, set its gauge to 300 mmHg (40.0 kPa). If using a Low or Standard Vacuum Regulator, set its gauge to 100 mmHg (13.3 kPa).
3. Open and close the fitting port several times.
4. With the fitting port occluded, the gauge should return to the setting listed in step 2 within a tolerance of:

   ± 38 mmHg (± 5.1 kPa) for high vacuum gauges

   or

   ± 10 mmHg (± 1.3 kPa) for standard vacuum gauges

   or

   ± 8 mmHg (± 1.1 kPa) for low vacuum gauges

8.5 Low Vacuum Regulators ONLY

1. Occlude the fitting port.
2. Rotate the suction control knob fully clockwise (increase).
3. Verify that the suction delivered does not exceed 135 mmHg ± 5 mmHg (18.0. kPa ± 0.7 kPa) or the maximum suction requested by the clinician.

Note: For setting the suction level limit, refer to suction level limit setting (Section 7.3. Suction Level Limit Setting - Low Models ONLY).

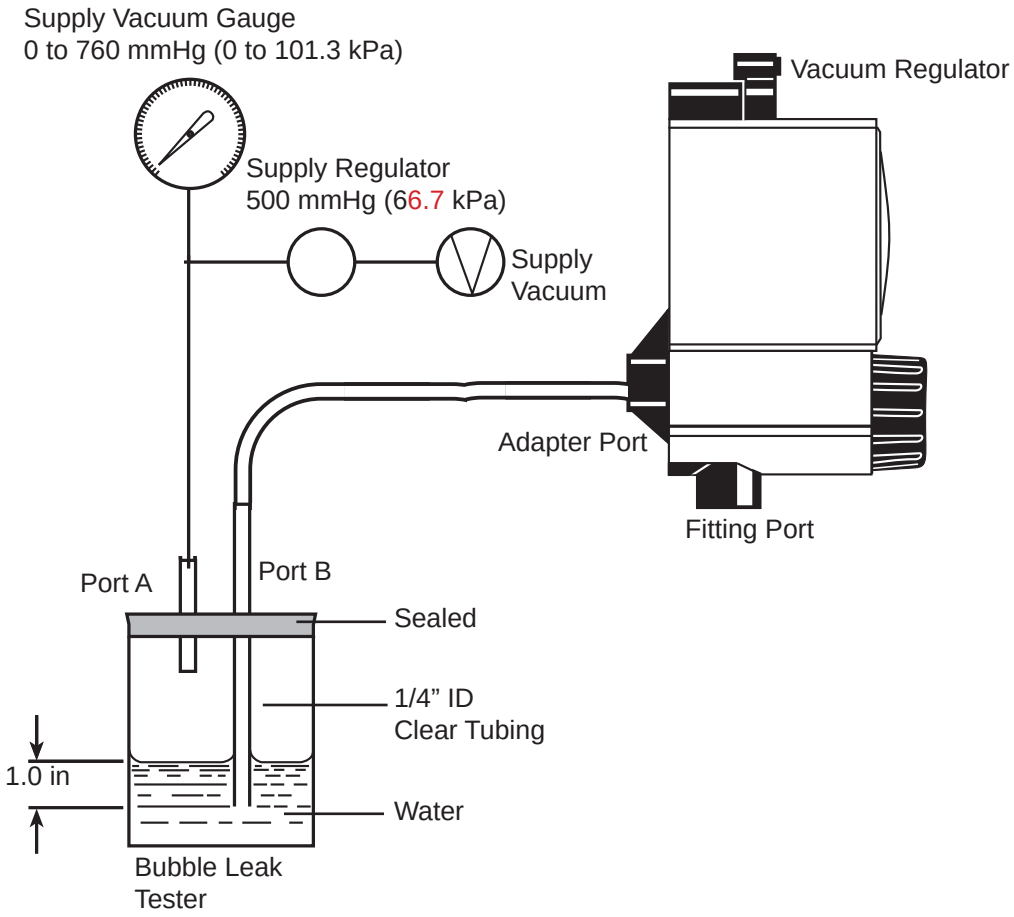
8.6 Bleed Test

1. Occlude the fitting port and set the vacuum level to 100 mmHg (13.3 kPa).
2. Turn the selector switch to O (Off) and observe the gauge needle. It must return to the zero range bracket or stop pin within 10 seconds.

8.7 Leak Test - Supply Side

1. Connect the supply vacuum tubing to port “A” of the bubble leak tester.
2. Connect port “B” of the bubble leak tester to the regulator adapter port.
3. Turn the mode selector switch to O (Off). Allow the fitting port to be open to air.
4. Wait 20 seconds. No More than 6 bubbles should appear in the next ten seconds.

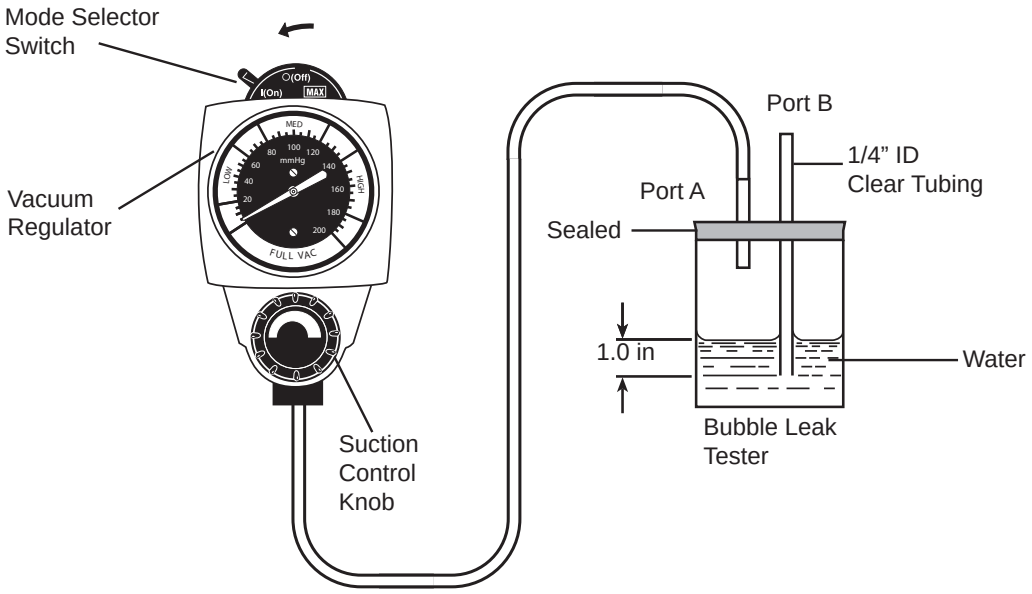
Important: Prior to venting port “A” of the bubble leak tester to atmosphere (i.e. turning the supply regulator off), ensure the tubing from port “B” has been disconnected from the adapter port of the vacuum regulator.



Bubble Leak Test - Supply Side

8.8 Leak Test - Patient Side

1. Connect the supply vacuum tubing to the regulator adapter port.
2. Connect the regulator fitting port to port “A” of the Bubble Leak Tester with tubing. Allow port “B” of the Bubble Leak Tester to be open to air.
3. Rotate the suction control knob a minimum of one full turn clockwise (increase). No bubbles should appear in the next ten seconds.
4. Rotate the suction control knob fully counter-clockwise (decrease).
5. Turn the mode selector switch to | (On). No bubbles should appear in the next ten seconds.



Bubble Leak Test - Patient Side

9.1 General Maintenance of Suction Equipment

WARNINGS

⚠ **The pre-use checkout procedure (Section 4.5 Pre-Use Checkout Procedure) must be performed before using this equipment on each patient. If the regulator fails any part of the pre-use checkout procedure, it must be removed from service and repaired by qualified service personnel.**

⚠ **Clean and sterilize all suction equipment if contaminated before disassembly, to ensure service personnel are not exposed to hazardous contamination. Continuous Vacuum Regulators should be kept in use or used on a rotating basis. Unused equipment may tend to deteriorate.**

Maintenance of the vacuum piping system is as important as maintenance of the suction equipment. The use of collection bottles with reliable shut-off valves, overflow safety trap assemblies and disposable suction filters will protect the regulator and piping system. The flow rate at the wall outlet should be checked on a yearly basis and suitable cleaning of the outlets should be performed. The flow rate measurement should meet local standards.

Routine maintenance and inspection are important to the performance of suction equipment. The following is a recommended list for care of suction equipment after each patient use.

1. Perform a thorough cleaning by washing all bottles, tubing, metal connectors, etc, and removing all residue.
2. Wipe all exterior surfaces with a solution of water and mild detergent.
3. Perform a careful visual inspection.
4. Check that the high flow disposable suction filter is clean and in good condition.
5. Check that all tubing is in good condition and connected securely to the correct ports.
6. Check the floats in the overflow safety trap and collection bottle for correct operation.
7. Perform the pre-use checkout procedure.

9.2 Recommended Maintenance Schedule

In addition to the Pre-Use Checkout Procedure, the following periodic maintenance should be performed.

9.2.1 Maintenance Schedule

Item	Minimum Frequency	Comments
Service Checkout	Every 12 months	If the regulator does not pass the service checkout procedure (Section 8 Service Checkout Procedure), refer to Section 6 Troubleshooting. Repair as necessary.
Elastometric components (O-rings, switch gasket, regulator module diaphragm, positive pressure safety valve) and internal filter	As required	Cleaning and replacement interval will depend greatly on hours of usage and environmental conditions. Replace and repair as necessary.

9.3 Repair Policy

WARNING

⚠ **Clean and sterilize all suction equipment before shipment or service to ensure transportation personnel and/or service personnel are not exposed to any hazardous contamination.**

CAUTIONS

⚠ Do not steam autoclave or liquid sterilize the Continuous Vacuum Regulator. Severe impairment to the operation of the regulator will result. The only acceptable method of sterilization is with gas (ethylene oxide).

⚠ Only competent individuals trained in the repair of this equipment should attempt to service it.

Do not use malfunctioning equipment. Make all necessary repairs. Have the equipment repaired by qualified service personnel or by Ohio Medical. Parts listed in the service manual for this product may be repaired or replaced by a competent, trained person who has experience in repairing devices of this nature. After repair, perform the service checkout procedure (Section 8 Service Checkout Procedure) to ensure that it is functioning properly, and complies with the published specifications.

9.4 Technical Assistance

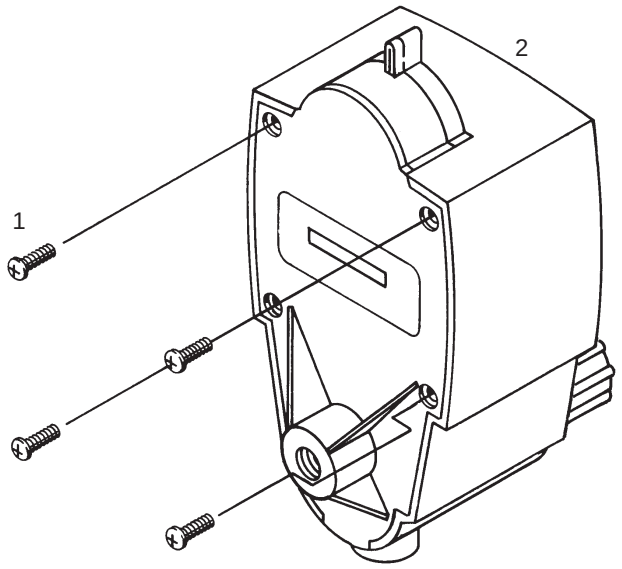
If technical assistance is required, contact Ohio Medical technical support or field operations listed on the back cover.

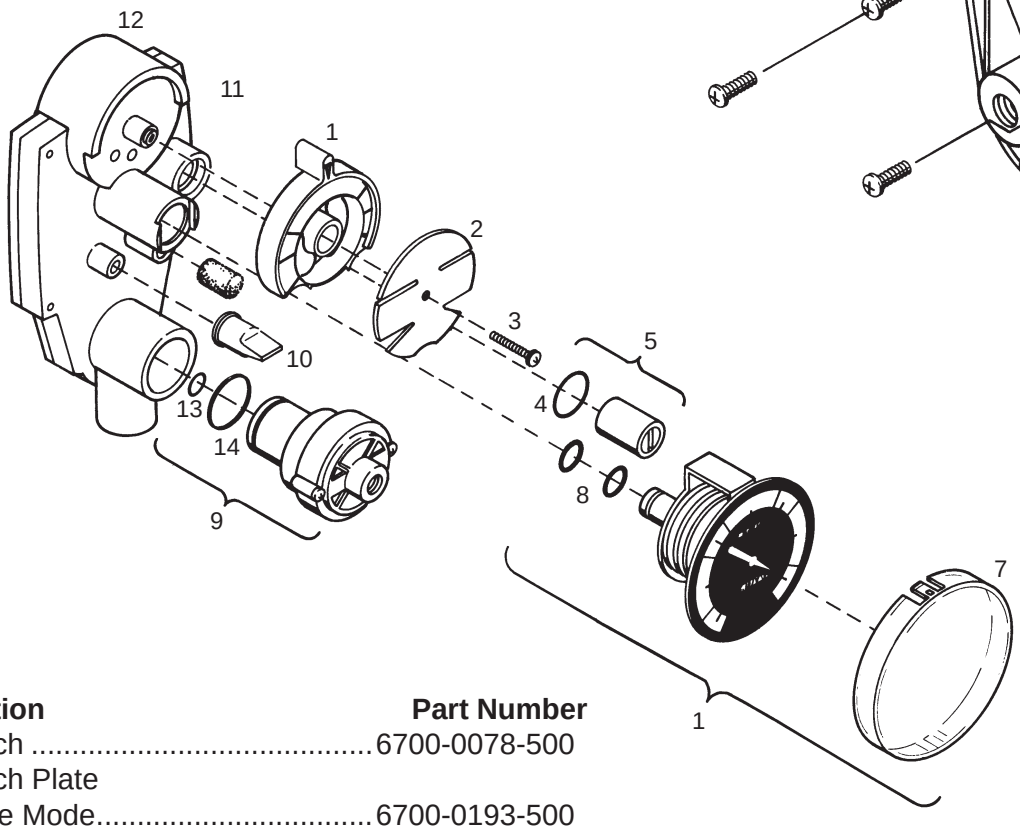
9.5 Return Instructions

1. Call 866-549-6446 for a returned goods authorization.
2. Clean and sterilize the vacuum regulator.
3. Package the vacuum regulator securely for protection; preferably in the original container.
4. Include a letter describing in detail any difficulties experienced with the vacuum regulator. Include the person, title, and telephone number to contact for functional questions.
5. If the vacuum regulator is under the warranty, include the warranty information that came with the device and a copy of the invoice.
6. Include a purchase order to cover repair of a regulator not under warranty.
7. Ship the vacuum regulator prepaid. Write your return address and billing address information on the package or letter that comes with the package.

For all repairs contact your nearest Ohio Medical office or authorized Ohio Medical distributor.

10.1 Illustrated Parts





Description	Part Number
1. Cover Screw (4)	6700-0152-400
2. Cover Assembly	
Low Models	6700-0629-850
Standard/High Models	6700-0628-850

Description	Part Number
1. Switch	6700-0078-500
2. Switch Plate	
Three Mode	6700-0193-500
Two Mode/Low	6700-0194-500
3. Screw	6700-0152-400
4. O-ring, Vacuum Relief Valve (Low Models Only)	6700-0135-500
5. Vacuum Relief Valve & O-ring (Low Models Only)	6700-0660-850
6. Gauge Assembly (Includes gauge, O-rings and lens)	
North American Standard, 0-200 mmHg	6700-0050-200
North American Low, 0-160 mmHg	6700-0050-202
North American High, 0-760 mmHg	6700-0050-201
International Low	6700-0050-205
International High	6700-0050-204
7. Lens	6700-0087-500
8. O-ring (2), Gauge	6700-0130-500
9. Regulator Module	
Standard/High Models	6700-1225-800
Low Models	6700-0428-800
10. Positive Pressure Safety Relief Valve	6700-0115-800
11. Filter (Internal)	0206-5159-300
12. Base	
North American Standard & High (Two & Three Mode)	6700-0018-203
North American Low	6700-0029-203
International Low	6700-0029-200
International High	6700-0018-200
13. O-ring, Stem	0210-0527-300
14. O-ring, Regulator Module	6700-0136-500

10.2 Service Kits

Standard and High Models 6700-0043-200
Includes the following parts:
O-ring (2), Gauge Filter (Internal)
Positive Pressure Safety Relief Valve
Regulator Module Replacement Kit

Low Models.....6700-0044-200
Includes the following parts:
O-ring (2), Gauge Filter (Internal)
Positive Pressure Safety Relief Valve
Regulator Module Replacement Kit
O-ring, Vacuum Relief Valve
Increase Label (Universal)
Regulator Module

Replacement Kit 6700-0030-700
Includes the following parts:

O-ring, Stem
O-ring
Diaphragm
Stem Screw
Cap Screw (3)

These parts are available only in kit form. If other parts are needed for replacement, the entire Module must be ordered (6700-1225-800).

O-rings and Filters Kit.....0221-5871-870
Includes the internal filter and 6 O-rings

Continuous Regulator Module (6).....6700-0028-700
Low Cont. Regulator Module (6).....6700-0190-700

Regulator Module Replacement
Parts Kit (6).....6700-0031-700

The following kits for U.S. regulators only
Standard Vacuum Gauge (4).....0205-8689-870
High Vacuum Gauge (4).....6700-0097-200
Low Vacuum Gauge (4).....6700-0098-200
Standard & High Backplate (4).....6700-0194-700
Low Backplate (4).....6700-0198-700

Installation procedure for Adapters/Probes and Fittings.

All adapters/probes and fittings should be sealed and installed properly to prevent leaks and to support the equipment when mounted. Both vacuum regulator ports are 1/8-27 NPTF tapered pipe threads. It is important to note that adapters/probes and fittings seal on the thread and may have threads exposed after they have been tightened properly.

Prior to installing the adapter/probe or fitting, seal the thread with Teflon® (PTFE) tape or one of the following lubricants:

Dow Corning® 111 (Ohio Medical P/N 6700-0074-200)

Ball Vac Kote® (37951M) (Ohio Medical P/N 0220-0091-300)

CAUTION

⚠ Do not use any Loctite® products to seal the threads (or products which contain Methacrylate Ester as an active ingredient).

The torque range for installing adapters/probes and fittings is 4.0 ft-lb (5.4 N-m) minimum to 10.0 ft-lb (13.6 N-m) maximum.

Adapters/probes and fittings which are not keyed for specific orientation, should be torqued to approximately 6.0 ft-lb (8.1 N-m).

Adapters/probes and fittings that are keyed to specific orientation, must be torqued initially to 4.0 ft-lbs. Additional torque is applied only until orientation is correct.

Ohio Medical Corporation®

always there | for life

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